law prohibits dispensing without prescription."

b. The drug products are labeled to comply with all requirements of the act and regulations, and the labeling bears adequate information for safe and effective use of the drug. The Indications are as follows:

Oral and Parenteral. For the relief of symptoms of depression. Endogenous depression is more likely to be alleviated than other depressive states.

Oral only. For adjunctive therapy in childhood enuresis.

3. *Marketing status.* a. Marketing of such drug products that are now the subject of an approved or effective new drug application or abbreviated new drug application may be continued provided that, on or before November 13, 1979, the holder of the application has submitted (i) a supplement for revised labeling as needed to be in accord with the labeling conditions described in this notice, and complete container labeling if current container labeling has not been submitted, and (ii) a supplement to provide updating information with respect to items 6 (components), 7 (composition), and 8 (methods, facilities, and controls) of new drug application form FD-356H (21 CFR 314.1(c)) to the extent required in abbreviated new drug applications (21 CFR 314.1(f)).

b. Approval of an abbreviated new drug application (21 CFR 314.1(f)) must be obtained prior to marketing such product. The application shall contain the information specificed in 21 CFR 314.1(f). The bioavailability regulations (21 CFR 320.21) require any person submitting an abbreviated new drug application after July 7, 1977, to include evidence demonstrating the in vivo bioavailability of the drug or information to permit waiver of the requirement. No waiver will be granted for imipramine hydrochloride in oral dosage forms. Marketing prior to approval of a new drug application will subject such products, and those persons who caused the products to be marketed, to regulatory action.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (secs. 502, 505, 52 Stat. 1050-1053 as amended (21 U.S.C. 352, 355)), and under the authority delegated to the Director of the Bureau of Drugs (21 CFR 5.82).

Dated: September 5, 1979.

J. Richard Crout,

Director, Bureau of Drugs.

FR Doc. 79-28556 Filed 9-13-79; 8:45]

BILLING CODE 4110-03-M

[Docket No. 79 N-0251]

Safety of Certain Food Ingredients; Opportunity for Public Hearing

Correction

In FR Doc. 79-23625 appearing on page 45759 in the issue of Friday, August 3, 1979, make the following corrections to the table on page 45760:

(1) In the first column, "carotent" should have read "carotene".

(2) In the third column "PB-241-950/AS; $9.25" should have read "PB-241-950/AS; A10; $9.25".

(3) In the last column, in the second line of item 1, ". . . Use of Food Chemical . . ." should have read ". . . Use of Food Chemicals . . .", and in the first line of item 2, "Letters, dated January 16, 1979, from . . ." should have read "Letters, dated January 16, 1979 and February 2, 1979, From . . .".

BILLING CODE 1505-01-M

[FDA-225-79-0011]

National Toxicology Program; Memorandum of Understanding With National Toxicology Program

Correction

In FR Doc. 79-23932 appearing on page 45762 in the issue of Friday, August 3, 1979, in the table at the bottom of page 45763, second line, change "Toxicology Date Management Systems" to "Toxicology Data Management Systems."

BILLING CODE 1505-01-M

Consumer Particiption; Open Meeting

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: This document announces a forthcoming Consumer Exchange Meeting to be chaired by the Acting Commissioner of Food and Drugs.

DATE: The meeting will be held at 1 p.m., Wednesday, September 26, 1979.

ADDRESS: The meeting will be held at the HEW North Building, Rm. 5051, 330 Independence Ave. SW., Washington, DC 20201.

FOR FURTHER INFORMATION CONTACT: Alexander Grant, Special Assistant to the Commissioner for Consumer Affairs (HF-7), Food and Drug Administration, Department of Health, Education and Welfare, 5600 Fishers Lane, Rm. 16-85, Rockville, MD 20857, 301-443-5006.

SUPPLEMENTARY INFORMATION: The purpose of the meeting is to exchange information between FDA officials and consumer representatives by providing an opportunity for consumer representatives to present their views directly to the Acting Commissioner and to the top managers of FDA, by seeking solutions to any problems agreed on during this communication, and by giving the agency an opportunity to discuss and communicate vital health and policy issues to the concerned public. Proposed discussion at the meeting will focus on the patient package insert proposal and minor tranquilizers.

Dated: September 6, 1979.

Joseph P. Hile,

Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-28426 Filed 9-13-79; 8:45 am]

BILLING CODE 4110-03-M

[FDA-225-79-4003]

Import Sampling; Memorandum of Understanding With the Customs Service

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has executed a memorandum of understanding with the Customs Service of the Department of the Treasury. The purpose of the memorandum of understanding is to set forth cooperative working arrangements under which FDA will perform import sampling services for the Customs Service.

DATES: The agreement became effective August 14, 1979.

FOR FURTHER INFORMATION CONTACT: Gary Dykstra, Regulatory Operations Section (HFC-22), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, MD 20857, 301-443-3470.

SUPPLEMENTARY INFORMATION: Pursuant to the notice published in the Federal Register of October 3, 1974 (39 FR 35697) stating that future memoranda of understanding and agreements between FDA and others would be published in the Federal Register, the agency is issuing the following memorandum of understanding:

Memorandum of Understanding Between the U.S. Customs Service and Food and Drug Administration

May 1979

The U.S. Customs Service of the Department of the Treasury and the Food and Drug Administration, hereby jointly agree to the following memorandum of understanding: